

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 5970/S35**

**CHEMISTRY REVIEW(S)**

MAY

CHEMIST'S REVIEW		1. ORGANIZATION HFD-160	2. NDA Number 5-970
3. Name and Address of Applicant (City & State) Elkins-Sinn, Inc. 2 Esterbrook Lane Cherry Hill, New Jersey 08003-4099		4. Supplement(s) Number(s) Date(s) S-035 8/23/90	
5. Drug Name Sotradecol	6. Nonproprietary Name Sodium Tetradecyl Sulfate Inj.		8. Amendments & Other (reports, etc) - Dates Y-028 9/5/90 Y-028 AM 10/15/90
7. Supplement Provides For: Conversion from screen to paper labeling			
9. Pharmacological Category Sclerosing agent	10. How Dispensed <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		11. Related IND(s)/NDA(s)/DMF(s)
12. Dosage Form(s) Intravenous Injection (2 mL ampul)	13. Potency(ies) 1% and 3%		
14. Chemical Name and Structure		15. Records/Reports Current <input type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input type="checkbox"/> Yes <input type="checkbox"/> No	
16. Comments: Supplement was submitted as "Change Being Effectuated" to convert from screen to paper labels.  Annual Report dated 9/5/90 was satisfactory except for an error in the total chloride specification for Sotradecol 3%. The specification was reported as NMT %, rather than %. This was corrected in an amendment to the <u>Annual Report</u> dated 10/15/90.			
17. Conclusions and Recommendations:  This supplement may be approved from a chemistry standpoint.			
18. REVIEWER			
Name Patricia Stewart	Signature		Date Completed 2/5/91

5-1-91